

## REMARKS

Upon entry of this amendment, claims 5-9, 12-14, 30, 33 and 42-48 are pending. Claim 10 has been canceled without prejudice or disclaimer as drawn to non elected subject matter. Applicant reserves the right to pursue these claims in a later application.

### **Rejection under 35 U.S.C. §101**

The Examiner rejected claims 5-10, 12-14, 30, 33 and 42-48 under 35 U.S.C. §101 as not supported by either a substantial asserted utility or a well established utility.

Applicants respectfully traverse. Applicants characterized this protein by conducting expression studies involving normal and cancerous cell lines to determine whether NOV8 was differentially expressed in cancer cell lines when compared to normal. (*See* pg. 209, lines 5-7). The results of these studies show that NOV8 is differentially expressed in lung, prostate, and breast cancers compared to the normal. (*See* pg. 209, lines 5-7). Thus, it is readily apparent from these results that the differential expression of NOV8 can be used to detect these cancers in a sample. The use of NOV8 to detect lung, prostate, and breast cancers in a sample is a specific, substantial asserted utility that satisfies the utility requirements of 35 U.S.C. §101.

The Examiner argues that utility is lacking because: “the expression studies show high expression in cell line SK-N-AS, as well as in a breast cancer cell line which are research tool cell line and does not appear to have any therapeutic nexus to a specific cancer treatment.” (Office Action, pg. 2)(emphasis added).

This assertion misses the point of Applicant’s argument. The claims do not relate to specific cancer treatments, nor are applicants required to demonstrate such a nexus in order to satisfy the utility requirement. Instead, Applicant is arguing that the utility of NOV8 lies in its ability to differentiate normal and cancerous cells in a sample. In other words, the utility of NOV8 lies in its ability to act as a diagnostic marker for certain types of cancer, and not necessarily for use as a specific cancer treatment (*see, e.g.*, p. 209, lines 9-10)(“[t]hus, expression of the NOV8 gene could be used as a marker...for lung, prostate and breast cancer”). Use of a gene as a diagnostic marker has long been recognized as sufficient to satisfy the utility requirement of 35 U.S.C. 101.

Since Applicants have made an assertion that the claimed invention is useful for a particular purpose, and such assertion would be considered credible by a person of ordinary skill in the art, a rejection based on lack of utility is not proper. Applicants respectfully request that the rejection of claims 5-10, 12-14, 30, 33 and 42-48 under 35 U.S.C. §101 be withdrawn.

**Rejections under 35 U.S.C. § 112, first paragraph**

The Examiner rejected claims 5-10, 12-14, 30, 33 and 42-48 under 35 U.S.C. §112 first paragraph as allegedly not supported by a substantial or a well-established utility. Applicants respectfully disagree. As discussed above, the specification clearly describes how to use the claimed invention and provides at least one asserted specific, substantial and credible utility. Therefore, Applicants respectfully submit that this rejection should be withdrawn.

**Rejections under 35 U.S.C. § 112, first paragraph**

Claim 10 is rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant respectfully disagrees. However, in order to expedite prosecution of the present subject matter, Applicant canceled claim 10, thereby rendering this objection moot.

**Priority**

The Examiner argues that the applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. §112 for claims 5-10, 12-14, 30, 33 and 42-48 for the reasons provided in the above sections.

Applicants respectfully traverse. The priority document relating to NOV8, U.S. Serial Application No. 60/244,995 ('995 Application) filed November 1, 2000 provides adequate support under 35 U.S.C. §112 to support a priority claim.

The '995 Application provides the nucleic acid and amino acid sequence of NOV8, thus satisfying the written description requirement of 35 U.S.C. §112. Moreover, the '995 Application states on page 8 that because of the expression pattern of NOV8, it is useful as a diagnostic marker, thereby satisfying the enablement requirement of 35 U.S.C. §112.

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In view of the above, Applicant respectfully requests withdrawal of this ground of rejection.

**Rejection under 35 U.S.C. § 102**

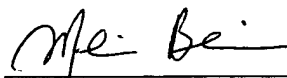
Claim 10 is rejected under 35 U.S.C. §102(b) by the Examiner as anticipated by Stripp et al. The Examiner contends Stripp discloses a nucleic acid encoding a protein which is 83% similar to the claimed polypeptide of SEQ ID NO:20.

Applicant respectfully disagrees. However, in order to expedite prosecution of the present subject matter, Applicant canceled claim 10, thereby rendering this objection moot.

**CONCLUSION**

Applicants respectfully request that the amendments and remarks made herein be entered and made of record in the file history of the present application. Applicants respectfully submit that the pending claims are in condition for allowance. Such action is respectfully requested. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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